REMARKS

Claims 1 and 9 have been amended to recite "[a] stable powderous formulation" and "[a] food, beverage, animal feed, cosmetic, or drug" in the singular rather than plural. Claims 2-5, 7, 8, 14, and 15 have been amended to recite "[t]he formulation", and claims 16 and 17 have been amended to recite "[t]he process." The noted amendments place the claims in better form for U.S. practice.

Claim 1 also has been amended to recite that "the fat-soluble active ingredient is selected from the group consisting of vitamin A, vitamin D, vitamin E, vitamin K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing." Support for this amendment is found in the specification at, for example, Paragraph 8, lines 1-14 and Example 2; and in original claim 6. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973); and MPEP §§ 608.01(o) and (l).

Claims 6 and 10 have been canceled without prejudice.

Claim 7 also has been amended to recite that the fat-soluble active ingredient is "present in" a plant or animal oil or fat. Support for this amendment is found in the specification at, for example, Paragraph 8, lines 1-14; and in original claims 6 and 7. (Id.)

Claims 11 and 12 have been amended to recite subject matter from now canceled claim 10. Support for these amendments is found in the specification at, for example, Paragraph 11; and in original claim 10. (Id.)

Claim 13 has been amended to recite the preparation of a "powderous' formulation. Support for this amendment is found in the specification at, for example, Paragraphs 11 and 12; and in original claim 13. (Id.)

Claims 18-23 have been added. Claim 18 recites "[a] stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked with a reducing sugar." Claim 18 is supported by the specification at, for example, Paragraphs 2, 9 - 12 , and Example 2; and original claims 1 and 8. (Id.)

Claim 19 is supported by the specification at, for example, Paragraphs 3-5 and Example 2; and original claims 2-5. (Id.)

Claim 20 is supported by the specification at, for example, Paragraph 8, lines 1-14 and Example 2; and in original claim 6.

Support for claim 21 is found in the specification at, for example, Paragraph 8, lines 1-14; and in original claims 6 and 7. (Id.)

Support for claim 22 is found in the specification at, for example, Paragraph 9, lines 1-3; and in original claim 8. (Id.)

Support for claim 23 is found in the specification at, for example, Paragraph 14; and in original claims 8 and 9.

No new matter has been added by any of the amendments.

Obviousness Rejection(s)

The Examiner maintained the rejection of claims 1-4, 6-8, and 10-13 under 35 U.S.C § 103, and made a new ground of rejection of claims 5, 9 and 14-17 under 35 U.S.C § 103 based upon the same cited documents. (Paper No. 20090710 at 3.)

Accordingly, claims 1-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fitchett et al., WO 1999/11143 ("Fitchett") in view of Perrier et al., U.S. Patent No. 5,912,016 ("Perrier") and Altemueller et al., U.S. Patent No. 6,423,364 ("Altemueller") as evidenced by Gerrard, *Trends in Food Science and Technology*, 13, 2002, pgs. 391-399 (Gerrard") and Rahman, Handbook of Food Preservation, Marcel Dekker, 1999 ("Rahman"). (Id.)

Each of Fitchett, Perrier, Altemueller, Rahman, and Gerrard have been summarized in the Response to Office Action Including Amendment, dated April 29, 2009 ("the prior Response").

In making the rejection, the Examiner made substantially the same assertions in the Final Action (Paper 20090710) from pages 3 to 8, as in the previous Action dated October 29, 2008 (Paper No. 20081014), from pages 5 to 10. The rejection was summarized in the prior Response from page 14, the last paragraph to page 18, the first full paragraph.

In the "Response to Arguments" section, the Examiner asserted that "Applicant's argument that there is no suggestion or motivation for cross-linking of protein in a matrix provided by Fitchett et al., is not convincing because Fitchett et al. is not relied upon for this teaching. Perrier et al. teaches particles of cross-liked plant proteins (title) and when combine [sic] with Fitchett et al. suggests cross-linked lupin protein formulations." (Paper No. 20090710 at 8.)

The Examiner also asserted that "Applicant's argument that there is no suggestion or motivation in Fitchett et al. for the claimed powderous formulation to comprise a fat-soluble active ingredient, is not convincing because Fitchett et al. is not

relied upon for this teaching. Perrier et al. teaches the inclusion of lipophilic active and the encapsulation of active ingredients (8:38-41) and when combine [sic] with Fitchett et al. suggests lupin protein formulations comprising an encapsulated fat soluble active ingredient." (Id. at 8-9.)

The Examiner further asserted that "Applicant's argument that there is no suggestion or motivation in Fitchett et al. to produce powderous formulations, is not convincing because Fitchett et al. is not relied upon for this teaching. Altemueller et al. teaches dried powderous unrefined soy protein material food ingredient (26:33-35) and when combined with Fitchett et al. suggests dried powderous formulations comprising lupin proteins." (Id. at 9.)

In addition, the Examiner asserted that "Applicant's argument that none of Fitchett, Perrier, or Altemueller disclose or suggest a formulation of a fat-soluble active ingredient in powder form, is not convincing because the references are relied upon as a combination." (Id.)

The Examiner also asserted that "Applicant's argument that Gerrard provides no disclosure that the cross-linking can be applied to lupin protein, is not convincing because the reactions taught by Gerrard can be applied to "food protein, either native or denatured" (see p. 392, Figure 1) and the described reactions would clearly apply to lupin food protein." (Id.)

Furthermore, the Examiner asserted that "Applicant's argument that achieving a stable powderous formulation would not have been predictable to one of skill in the art, is not convincing because Altemueller et al. further teaches drying of the processed plant protein material (26:33-35), and it would have been obvious to the

skilled artisan that powderous form would have been more stable than liquid formulations because chemical products, especially easily degradable food products, would have degraded more slowly in the dried form (i.e. a more stable product)." (Id. at 9-10.)

Arguments presented previously on the record are incorporated herein.

To forward prosecution in the present application, claim 1 has been amended to recite "a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked and the fat-soluble active ingredient is selected from the group consisting of vitamin A, vitamin D, vitamin E, vitamin K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing."

Although not a rejected claim, newly presented claim 18 is noted here, which recites "[a] stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked with a reducing sugar."

Returning to claims that have been rejected, to forward prosecution in the present application, claim 11 has been amended to recite "[a] process for the preparation of a formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition, wherein a reducing sugar is added and the composition is submitted to cross-linking by heating. And claim 12 has been amended to recite "[a] process for the preparation of a formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin

protein composition, wherein the composition is submitted to cross-linking by treatment with a cross-linking enzyme. In addition, claim 13 has been amended to recite "[a] process for the preparation of a *powderous* formulation..." (emphasis added.)

As previously noted on the record, it is well settled the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

As also previously noted, the rejection should have, but did not, explain on the record ***why*** one skilled in this art would modify the disclosures of the cited documents in the manner proposed by the Examiner to arrive at the claimed process. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (citing *KSR*) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). In light of this decisional authority, the rejection is incomplete. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

Fitchett differs in numerous ways from the presently claimed stable powderous formulation. There is no teaching, suggestion, or motivation provided by

Fitchett to achieve the claimed powderous formulation. As a brief summary of prior arguments, first, Fitchett does not disclose, suggest or provide motivation for a ***powderous*** formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition. Second, Fitchett provides no suggestion or motivation for the claimed powderous formulation wherein the protein in the matrix is ***cross-linked***. Rather, Fitchett discloses "oil:water emulsions stabilized by lupin protein compositions and to gels comprising lupin protein compositions." (Abstract, line 2.) No suggestion or motivation for cross-linking of protein in a matrix in a powderous formulation is provided by Fitchett. Third, ***Fitchett lacks any enabling disclosure*** of preparing a powderous formulation, let alone a powderous formulation as claimed in which the protein in the matrix is cross-linked. Fourth, there is no suggestion or motivation in Fitchett for the claimed powderous formulation to comprise a ***fat-soluble active ingredient*** in the matrix, as claimed. The Examiner is encouraged to review the previous arguments in full on the record.

We also note that Fitchett discloses the use of lupin protein compositions to "[stabilize] food systems that use high fat and water mixtures, such as comminuted meat products (e.g., sausages) and dairy product replacers." (Page 2, lines 35-37 and Page 3, lines 4-7.) Moreover, the Examples disclose the preparation of a poultry skin emulsion (Example 1), frankfurter as an emulsion (Example 2), and a non-dairy spread (Example 3). Thus, Fitchett stabilizes a substance having a "solid protein content" in addition to fat and water. (Page 3, lines 4-9.) The substance that is stabilized in accordance with the disclosure of Fitchett does not suggest a fat-soluble active

ingredient as claimed, none the less in a matrix formed from a native lupin protein composition wherein the protein is cross-linked.

In connection with amended claim 1, it is submitted that Fitchett does not disclose, suggest, or provide motivation for the claimed stable powderous formulation in which the fat-soluble active ingredient in the matrix is selected from the group consisting of vitamin A, vitamin D, vitamin E, vitamin K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing. Nor does Fitchett disclose, suggest or provide motivation for the stable powderous formulation of claim 18 "comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked with a reducing sugar."

We note that Fitchett discloses the use of lupin protein in a variety of physical states, "i.e., whether native, more or less denatured, derivatized, sub-fractionated, etc." (Page 3, lines 33-35.) And, Fitchett discloses processes in which "the structural integrity and/or solubility of the lupin protein may be decreased (at least to some extent) by the treatment (without necessarily compromising, and in some circumstances actually improving, functionality). Thus, the treatment may effect a degree of denaturation of the native lupin proteins..." (Page 5, lines 28-31.) In particular, Fitchett discloses that "[i]t may ... be desirable to derivatize or physically modify the lupin protein, for example, by (at least partially) denaturing the proteins (e.g., by heating) or by (e.g., partial) enzymic digestion (e.g., protease treatment to yield peptides)." (Page 6, lines 8-10.) Fitchett further discloses that this and other disclosed approaches "can be used to modify the fat/water binding characteristics of the lupin protein and so optimize the emulsion stabilizing properties..." (Page 6, lines 11-13.)

In view of the above, Fitchett indicates that the variety of physical states of lupin protein may be equivalent in terms of emulsion stabilizing properties. Moreover, Fitchett discloses that denaturation may "in some circumstances actually [improve] functionality." (Page 5, line 30.) Fitchett thus provides no suggestion or motivation to choose native lupin protein out of the variety of disclosed physical states of lupin protein in the claimed powderous formulation. Furthermore, Fitchett's disclosure of treating lupin protein with heat or enzymic digestion, e.g., protease treatment, involves breaking down, i.e., denaturation of the protein. As noted, Fitchett discloses treatments that denature or break down lupin protein, whereas cross-linking which forms a matrix in accordance with the claimed invention reinforces the protein by forming additional linkages and connections. As disclosed in the specification with regard to the claimed invention, "cross-linked formulations have been found to exhibit increased stability." (Para 10, lines 5-7) (emphasis added.) Fitchett's disclosure of denaturing lupin protein for emulsion stabilization is antithetical to cross-linking native lupin protein to form a matrix, and achieve the claimed stable powderous formulation comprising a fat soluble active ingredient in the matrix.

As is well settled, to do what the prior art teaches against is the very antithesis of obviousness. See, *e.g., In re Rosenberger*, 156 USPQ 24, 26 (CCPA 1968) and *In re Buehler*, 185 USPQ 781, 787 (CCPA 1975). At a minimum, the fact that Fitchett suggests that procedures involving lupin denaturation are equivalent to other procedures using lupin protein in an emulsion indicates that there is no suggestion or motivation provided by Fitchett to use native lupin protein to achieve the claimed stable powderous formulation, let alone where the stable powderous formulation comprises a

fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked. Furthermore, Fitchett provides no teaching, suggestion, or motivation regarding native lupin protein in the matrix cross-linked with a reducing sugar.

The Examiner cannot simply ignore the numerous and varied equivalents disclosed by Fitchett, and yet provide no reason why one skilled in the art would have chosen the aspects of Fitchett that the Examiner contends are similar to the claimed invention, and then make the asserted modifications, also without a sufficient indication as to why, to allegedly result in the claimed powderous composition, whether in view of Fitchett alone or in combination with any or all of the secondary documents cited. Moreover, there are disclosures of equivalent embodiments in Fitchett that could lead one skilled in the art in a direction away from the claimed invention. The Examiner has not and cannot reconcile these deficiencies in the rejection regarding Fitchett.

Furthermore, Fitchett provides no disclosure from which one skilled in the art would glean any information regarding how one could prepare a matrix using native lupin protein, and ultimately the claimed stable powderous formulation. In connection with the lack of enabling disclosure in Fitchett, it is pointed out, as noted above, that the heat treatments of Fitchett are disclosed as being denaturing to the lupin protein, which procedure is counter to cross-linking to form a matrix. More to the point, nowhere in Fitchett is it disclosed or suggested to add a reducing sugar and apply heat or treat with a cross-linking enzyme such as a transglutaminase to effect cross-linking, as in accordance with the claimed invention. (See, e.g., the specification at paragraphs 9-11.)

Neither Perrier, nor any of the other cited documents, alone or in combination, cure the deficiencies of Fitchett. Perrier's disclosure of particles, such as microcapsules and nanocapsules, and methods for encapsulating substances fails to disclose, suggest or provide motivation for the claimed stable powderous formulation. It bears repeating from the record that Perrier discloses that "[t]hese particles comprise, at least on the surface, a wall formed of plant proteins crosslinked ... by means of interfacial crosslinking between the plant proteins and an acylating polyfunctional crosslinking agent comprising at least two acylating groups, covalent bonds being formed between the acylatable groups of the proteins and the acyl groups of the acylating polyfunctional crosslinking agent." (Abstract, lines 1-8) (emphasis added.) Perrier further discloses that the produced particles are "especially spheres or capsules such as nanospheres or nanocapsules and microspheres or microcapsules, which ... encapsulate substances, particularly active principles...". (Col. 8, lines 35-39) (emphasis added.)

Furthermore, Perrier discloses the use of an acylating polyfunctional cross-linking agent, for example, "a diacid halide, preferably a diacid chloride." (Abstract, lines 4-5; Col. 3, lines 38-40.) Perrier discloses "a process for the manufacture of the ... particles with a wall formed of crosslinked plant proteins," which uses interfacial cross-linking, for example, from Col. 6, line 66 to Col. 8, line 45. Perrier also discloses that the polyfunctional cross-linking agent added to an emulsion of the "oil-in-water" type, for example, forms "a membrane around the dispersed hydrophobic droplets to give particles with hydrophobic contents, consisting of capsules..." (Col. 4, lines 14-26.) Perrier thus discloses that the interfacial cross-linking results in cross-

linking which forms a wall or surface around the oily phase. This is known to one of skill in the art as encapsulation.

Consistent with Perrier's disclosure of the use of interfacial cross-linking, one skilled in the art would have understood that interfacial polymerization is effected using a specific type of cross-linking agent which is an acrylating polyfunctional crosslinker. Attached for the Examiner's reference as Exhibit A is an excerpt from Ullmann's Encyclopedia of Industrial Chemistry, John Wiley & Sons (2005), p. 11, under section 2.1.2, which has the heading "Interfacial Polymerization" (which excerpt is from Hamielec, A. E., et al., Polymerization Processes, published online June 15, 2000) ("Ullmann's Encyclopedia"), which indicates that "[i]n interfacial polymerization, polymers are formed at or in the vicinity of the phase boundary of two immiscible monomer solutions." The process of performing interfacial polymerization is disclosed in Ullmann's Encyclopedia, for example, using acid chlorides for step-growth polymerization. (Id.) One skilled in the art would have understood, from the disclosure in Ullmann's Encyclopedia, for example, that interfacial polymerization is specific to producing polymerization at or in the vicinity of the phase boundary of immiscible solutions.

Perrier's disclosure of interfacial polymerization which results in cross-linking to form a wall or surface, i.e., encapsulation of a desired substance, provides no suggestion or motivation to produce cross-linking which results in a matrix, as in the claimed stable powderous formulation. In the claimed formulation, the fat-soluble active ingredient is finely distributed in the matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

In addition, Perrier does not enable the preparation of either the matrix or the powderous formulation comprising a fat-soluble active ingredient in a matrix, as claimed. As one skilled in the art would have known, interfacial polymerization results in encapsulating a substance, and would not result in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked, as claimed. Moreover, Perrier provides no disclosure regarding how to prepare the matrix, let alone the claimed stable powderous formulation. Perrier provides no disclosure, suggestion or motivation regarding the use of a reducing sugar to effect cross-linking to achieve the matrix, for example, in claim 1, and as recited in claims 8 and 18, or the process, *e.g.*, of claims 11 and 13; nor does Perrier provide any disclosure, suggestion or motivation regarding the use of a cross-linking enzyme such as transglutaminase to achieve the matrix, for example, in claim 1, or the process as recited in claims 12, 16, and 17. It is also noted that the disclosure in Ullmann's Encyclopedia does not in any way indicate the use of a reducing sugar or a cross-linking enzyme such as transglutaminase in connection with interfacial polymerization, the process used according to Perrier.

It is further noted that the present specification discloses that treatment with a transglutaminase enzyme can be achieved according to U.S. Patent No. 5,156,956 to Motoki et al. ("Motoki"). (Para 10.) Motoki is attached as Exhibit B. Motoki discloses that "[t]he transglutaminases form intramolecular or intermolecular... cross-linking..." (Col. 1, lines 16-17.) Furthermore, the specification discloses that cross-linking resulting from heat treatment of the reducing sugar with the protein and treatment with cross-linking enzymes such as transglutaminase "<u>have been found to exhibit increased stability</u>." (Para 9-10) (emphasis added.)

One skilled in the art simply would not look to a disclosure of encapsulation using interfacial polymerization in attempting to make a cross-linked matrix, and achieve a stable powderous formulation, as claimed. Furthermore, one would not look to Perrier to achieve a matrix in which native lupin protein is cross-linked with a reducing sugar. And, to reiterate from above, Perrier does not disclose or suggest a powderous formulation.

At bottom, there is simply no disclosure, suggestion or motivation in Perrier for making a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked, let alone cross-linked with a reducing sugar.

Perrier fails to fill the gaps in Fitchett and, as demonstrated below, none of the other documents relied on by the Examiner remedy the deficiencies in Fitchett (and Perrier).

Altemueller's functional food ingredient comprising an unrefined plant protein material wherein the functional food ingredient is hydrated, partially denatured and dried, fails to provide a suggestion or motivation to achieve the claimed stable powderous formulation. Altemueller discloses that the preferred plant protein is soy. (See, e.g., Col. 5, lines 60-61.) Altemueller discloses hydrating the unrefined soy protein with water (Col. 24, lines 7-8), and treating to "irreversibly partially denature at least a portion of the soy protein in the hydrated unrefined soy protein material." (Col. 24, lines 64-66.) This material is dried, according to Altemueller, for example, by flash vaporization followed by spray-drying. (Co. 25, lines 63-65.) A dried, partially-denatured unrefined soy protein results. (Abstract, lines 6-10.)

As noted above with regard to Fitchett, denaturing a soy protein as disclosed by Altemueller is antithetical to cross-linking native lupin protein to form a matrix and achieve a stable powderous formulation, as claimed. And there is no fat-soluble active ingredient taught or suggested by Altemueller, in a matrix comprising a powderous formulation, as claimed. Furthermore, there is no disclosure, suggestion or motivation provided by Altemueller for making a dried emulsion. The dried lupin composition of Altemueller is simply not comparable to the stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked. And at least for this reason, one skilled in the art would not look to Altemueller to modify Fitchett to obtain the presently claimed subject matter.

And, none of Fitchett, Perrier, or Altemueller discloses or suggests a formulation of a fat-soluble active ingredient in powder form, as claimed.

Moreover, neither Rahman nor Gerrard, alone or considered together as "evidence", cure the deficiencies of the Examiner's combination. Rahman's disclosure of general aspects of drying and food preservation for any dried food composition do not provide motivation for, nor an indication as to how to make, the claimed powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked, including with a reducing sugar.

Gerrard's disclosure is a general overview of various types of crosslinking in food including Maillaird crosslinking. Gerrard provides no disclosure that the crosslinking can be applied to native lupin protein. Gerrard fails to provide motivation

for the claimed powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

As noted above, Fitchett discloses a variety of physical states of lupin protein as equivalent in terms of emulsion stabilizing properties, and also discloses that denaturating or breaking down lupin protein may improve these properties. There is no suggestion to choose native lupin protein, and no disclosure of cross-linking to prepare a matrix, and no powderous formulation. There is no basis to combine Fitchett with Perrier, which is directed to polymerizing at the phase intersection to form a wall and encapsulate a substance. Neither Fitchett nor Perrier disclose the use of a reducing sugar.

And if such a combination of documents were proper, which we submit it is not, it could not result in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked, comprising a stable powderous formulation. At best, particles of an encapsulated substance may be produced. In adding the dried, partially-denatured unrefined soy protein of Altemueller to the Examiner's combination, the incongruity again underscores the inappropriateness of the combination. At best, again, the result may be particles of an encapsulated substance which do not suggest a cross-linked matrix, as claimed.

When considered together, Fitchett's emulsion or gel in combination with Perrier's microcapsules or nanocapsules and Altemueller's dried unrefined plant protein which may be used as a functional food ingredient, alone or in combination, do not lead one skilled in the art to the claimed stable powderous formulation. These documents

have such differing and varied disclosure of formulation options such that the Examiner could only have made this combination by an improper hindsight analysis. Nor do Gerrard, which discloses a dry powder for food preservation and/or Rahman, which discloses protein crosslinking generally, which are cited allegedly as "evidence" by the Examiner, cure the deficiencies in the Examiner's proposed combination.

In view of all of the foregoing, one skilled in the art would not have been able to predict success in achieving a stable powderous formulation, as claimed.

One skilled in the art would have known that numerous formulation options for a fat-soluble active ingredient would be available. Thus, known formulation options were not "finite, identified, and predictable", as in the facts presented in *KSR Int. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). In *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ 1161, 1171 (Fed. Cir. 2008), the Court of Appeals for the Federal Circuit indicated that the Supreme Court in *KSR* "did not create a presumption that all experimentation in fields where there is already a background of useful knowledge is 'obvious to try,' without considering the nature of the science or technology."

The Court of Appeals for the Federal Circuit has reaffirmed that "hindsight claims of obviousness" are improper. In distinguishing between fact patterns where a combination of known elements may or may not be proper, the Federal Circuit clearly articulated that simply varying all possible parameters until the claimed invention is arrived at in the absence of either an indication of which parameters to vary or an indication of which of many possible choices is likely to be successful is impermissible hindsight reconstruction. Indeed, the Federal Circuit concluded:

> Similarly, patents are not barred just because it was obvious "to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 2009 WL 1313321 at *5 (Fed. Cir. May 13, 2009), citing *In re O'Farrell*, 853 F.2d at 903.

Clearly, the Examiner's rejection is based on impermissible hindsight reconstruction and is improper.

Moreover, as in the *Abbott* case involving producing extended release formulations, one skilled in the art would not have predicted success in achieving the presently claimed stable powderous formulation, as "knowledge of the goal does not render its achievement obvious." *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ at 1172 (affirming the district court's determination that Abbott is likely to prevail in its claim that the patent is valid, and upholding the grant of a preliminary injunction).

In view of the foregoing, it is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

Obviousness Type Double Patenting Rejection

Claims 1, 6-9, 11 and 13 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 8,12-14,16 and 17 of copending Application No. 10/564,635 ("the '635 Application") in view of Perrier.

In making the rejection, the Examiner made essentially the same assertions as were made in the Office Action dated October 29, 2008, Paper No. 20081014. (Paper No. 20090710 at 10-12.) The rejection has been summarized in the prior Response.

In the "Response to Arguments" section, the Examiner asserted that "Applicant's argument that Perrier simply does not disclose or suggest a formulation of a fat-soluble active ingredient in powder form, is not convincing because the copending claims of '635 recite --stable powderous formulations--, coextensive with the preamble of the instantly rejected claims." (Id. at 13.)

To forward prosecution, amendments as noted above were made to the claims.

Arguments submitted previously on the record are incorporated here.

As acknowledged by the Examiner, "[t]he difference between Copending '635 and the instant claimed invention is that copending '635 does not explicitly teach the use of lupin protein for the primary cross-linking protein." (Id. at 12.) The '635 application claims the presence of "a milk protein composition" (e.g., claim 1) in the claimed stable powderous formulation, which does not suggest the presence of native lupin protein.

Arguments regarding Perrier provided above are incorporated here. In brief, Perrier discloses encapsulating substances by means of interfacial polymerization. Perrier's disclosure of interfacial polymerization which results in cross-linking to form a wall or surface, i.e., encapsulation of a desired substance, provides no suggestion or motivation to produce cross-linking which results in a matrix, as in the claimed stable powderous formulation. In the claimed formulation, the fat-soluble active ingredient is finely distributed in the matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

Also, Perrier does not enable the preparation of either the matrix or the powderous formulation comprising a fat-soluble active ingredient in a matrix, as claimed. Perrier provides no teaching, suggestion or motivation regarding the use of a reducing sugar, to effect cross-linking to achieve the matrix for example, in claim 1, and as recited in claims 8 and 18, or the process, *e.g.*, of claims 11 and 13; nor does Perrier provide disclosure, suggestion or motivation regarding the use of a cross-linking enzyme such as transglutaminase to achieve the matrix, for example, in claim 1, or the process as recited in claims 12, 16, and 17. One skilled in the art simply would not look to a disclosure of encapsulation using interfacial polymerization in attempting to make a cross-linked matrix, and achieve a stable powderous formulation, as claimed. Furthermore, one would not look to Perrier to prepare a matrix of native lupin protein which is cross-linked with a reducing sugar.

Moreover, Perrier does not disclose or suggest a powderous formulation.

At bottom, there is simply no teaching, suggestion or motivation in Perrier for making a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked, including with a reducing sugar.

A combination of the claims of the '635 Application and Perrier would not result in the presently claimed invention.

Accordingly, It is submitted that the rejection has been overcome. Reconsideration and withdrawal of the rejection are requested.

In view of all of the foregoing, entry of the amendments and withdrawal of all outstanding objections and rejections is respectfully requested. It is submitted that the application is in condition for allowance. Issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

By: _____

Eileen M. Ebel
Registration No. 37,316
BRYAN CAVE LLP
1290 Avenue of the Americas
33rd Floor
New York, NY 10104-3300
Phone: (212) 541-2000
Fax: (212) 541-4630

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 23, 2009.

_____
Eileen M. Ebel, Reg. No. 37,316